IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 7 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

REPLY BRIEF IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS OF BRUCE ROSENZWEIG, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson (collectively "Ethicon") submit this reply brief in further support of their motion to exclude certain general opinions of Bruce Rosenzweig, M.D.

I. Plaintiffs' broad and vague attempts to rely on unspecified prior reports of Dr. Rosenzweig is improper.

Ethicon simply requests that Dr. Rosenzweig rely on one expert report rather than vaguely referencing numerous past reports and requiring Ethicon to guess about what opinions he intends to provide at trial. Given Plaintiffs' failure to oppose Ethicon's motion to strike Plaintiffs' "Notice of Adoption of Prior Expert Reports and Testimony of Dr. Bruce Rosenzweig" (Doc. 4045), there is no basis for Plaintiffs to take issue with Ethicon's challenge to Dr. Rosenzweig's adoption of prior reports here.

II. The Court should preclude Dr. Rosenzweig from testifying that non-synthetic mesh procedures are a safer alternative.

In their response, Plaintiffs claim that "[t]he issue is whether Dr. Rosenzweig's opinions regarding the safety of non-mesh procedures should be universally declared as irrelevant to all trials in Wave 7—regardless of the state law that applies . . . ." (Doc 5482, pp. 4-5) (emphasis

added). But there is only one remaining case in Wave 7 in which Dr. Rosenzweig has been designated to provide general opinions—Annette Sutphin (No. 2:14-cv-25603)—and West Virginia law applies in that case. *See* Case No. 2:14-cv-25603, Doc. 26, pp. 4-5.

Thus, the issue in this remaining case is identical to the issue in *Mullins v. Johnson & Johnson*, 2017 WL 711766 (S.D.W. Va. Feb. 23, 2017). There, the Court found that "[e]vidence that a surgical procedure should have been used in place of a device is not an alternative, feasible design in relation to the TVT." *Id.* at *2. Applying West Virginia law to this *Sutphin* case in the same way that it applied West Virginia law in *Mullins*, the Court should preclude Dr. Rosenzweig from suggesting to the jury that non-mesh procedures and pubovaginal slings are safer alternatives to TVT.

Indeed, the Illinois court decision cited in Plaintiffs' response, *Herrera-Nevarez v. Ethicon, Inc.*, 2017 WL 3381718 (N.D. Ill. Aug. 6, 2017), is wholly inapplicable, because Illinois law—unlike West Virginia law—does not require a plaintiff to show a safer, feasible alternative.

The Court should also reject Plaintiffs' alternative argument that "the Court should allow testimony about pubovaginal slings/native tissue repair" on the basis that "there is substantial additional material involved in a pubovaginal sling" such that it purportedly is a "product." (Doc. 5482, pp. 8-9). But those slings are not manufactured; they are made from bodily tissue.

In any event, Plaintiffs ignore the Court's central tenet in *Mullins* that "other surgeries or procedures do not inform the jury on *how* the TVT's design could have feasibly been made safer to eliminate the risks that cause the plaintiffs' injuries" and that "the plaintiff must provide evidence of an alternative, feasible design for the *product* at issue—in this case, the TVT." *Mullins*, 236 F. Supp. 3d at 943-44 (emphasis in original). Thus, references to pubovaginal slings would not inform the jury about how TVT could be designed differently so that it would

be safer; instead, Dr. Rosenzweig would merely be suggesting that TVT should not be manufactured at all.

Further, even if pubovaginal slings were a product and share the same general purpose, they are a completely different kind of product with their own unique advantages and disadvantages with their own unique surgery, and therefore, may not be compared as a safer alternative. *See Theriot v. Danek Medical Inc.*, 168 F.3d 253, 255 (5th Cir. 1999) (rejecting hooks and wires as an alternative to screws, because the choice is up to the surgeon).

Plaintiffs' reliance on *Keffer v. Wyeth*, 791 F. Supp. 2d 539 (S.D.W. Va. 2001), is misplaced. There, the court found that the comparable product must have the same "fundamental and necessary" characteristics – which two versions of the same drug, one synthetic and one natural, were found to have. *Id.* at 548-50.

Here, pubovaginal autologous slings are not two versions of the same device. A pubovaginal sling is made of natural material and it is inserted through the abdomen, tied in place with suture, and his a limited life span. It, thus, requires a more invasive surgery, demands greater hospital time, employs different methods of securing the sling to the internal organs, and calls for different surgical skills dependent on the experience and training of the surgeon. It serves distinct purposes and does not serve the purposes for which TVT was designed, including but not limited to minimal invasiveness.

III. The Court should preclude Dr. Rosenzweig from testifying that devices with a different type of mesh are safer alternatives for the surgical treatment of SUI.

Ethicon adopts its Wave 3 arguments on this issue set forth in Section I of Doc. 2818 and Doc. 3024.

IV. The Court should preclude Dr. Rosenzweig from criticizing the cut of TVT mesh.

Ethicon adopts its Wave 3 arguments on this issue set forth in Section II of Doc. 2818 and Doc. 3024.

V. The Court should limit Dr. Rosenzweig's product warning opinions.

Ethicon adopts its Wave 3 arguments on this issue set forth in Section III of Doc. 2818 and Doc. 3024.

VI. The Court should preclude Dr. Rosenzweig from testifying about alleged mesh degradation and other biomaterials opinions.

Ethicon adopts its Wave 3 arguments on this issue set forth in Section IV of Doc. 2818 and Doc. 3024.

VII. The Court should preclude Dr. Rosenzweig from testifying about duties allegedly owed by a manufacturer.

A. Testing

Plaintiffs offer no basis for this Court to depart from its prior rulings that Dr. Rosenzweig is not qualified to testify about "the appropriate testing a medical device manufacturer should undertake." *In re: Ethicon,* 2016 WL 4500765, at *5. In any event, Dr. Rosenzweig certainly should not be allowed to speculate about what testing would have revealed, had it been performed.

B. Adverse Event Reporting

As with Dr. Rosenzweig's opinions about product testing, Plaintiffs are seeking to misuse Dr. Rosenzweig "as a conduit for corporate information by testifying about the extent of Defendants' adverse event reporting." *Walker v. Ethicon, Inc.*, 2017 WL 2992301, at *6 (N.D. Ill. June 22, 2017). The Court should disallow any such testimony.

C. Training

Plaintiffs do not contest Ethicon's challenge to Dr. Rosenzweig's opinions about physician training.

VIII. The Court should exclude Dr. Rosenzweig's marketing opinions.

Plaintiffs do not contest Ethicon's challenge to Dr. Rosenzweig's marketing opinions.

IX. The Court should preclude Dr. Rosenzweig from testifying about MSDS sheets.

Ethicon adopts its Wave 3 arguments on this issue set forth in Section VIII of Doc. 2818 and Doc. 3024.

X. The Court should not allow other opinions that are beyond Dr. Rosenzweig's expertise and/or otherwise improper.

Ethicon adopts its Wave 3 arguments on this issue set forth in Section IX of Doc. 2818 and Doc. 3024.

CONCLUSION

For the reasons set forth and referenced herein, Defendants respectfully request that the Court grant their Motion to Exclude the Testimony of Bruce Rosenzweig, M.D.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I, William M. Gage, certify that on this day I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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